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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,194	06/26/2003	Daniel J. Potter	11533US.00	7602
36802	7590	10/01/2008	[REDACTED]	EXAMINER
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			[REDACTED]	BHATIA, AARTI
			[REDACTED]	ART UNIT
			[REDACTED]	PAPER NUMBER
				3763
			[REDACTED]	MAIL DATE
			[REDACTED]	DELIVERY MODE
			10/01/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/609,194	POTTER, DANIEL J.	
	Examiner	Art Unit	
	Aarti Bhatia	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 9/04/2008.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This Office Action is based on the 10/609,194 application filed on 06/26/2003.

Claims 1-12, as amended on 9/04/2008, are currently pending and have been considered below.

Response to Amendment

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,312,355 to Lee in view of U.S. Patent No. 6,083,207 to Heck.

Lee discloses a tearable hemostasis valve (14) comprising: a valve body (16); a first and second grip tab (38, 40) attached to said valve body at a first and second point (it is the Examiner's position that the interior of the grip tabs contact the valve body in the general center area of the valve assembly, the center axis being substantially a

Art Unit: 3763

common point for the grip tabs to meet); a score line (42) disposed on said valve body between said first and second points; a first self-sealing membrane (22) disposed within said valve body; and a snap-fit arrangement coupled to a distal end of said valve body (see 16b in figure 2), wherein said snap-fit arrangement comprises a cavity disposed in said valve body; and an annular sidewall (see base of 16b) defining an opening in communication with said cavity, further comprising a score in said first membrane (column 8, lines 1-2).

Lee teaches wherein the snap and fit arrangement is adapted to couple into an **inner** surface of an annular hub of a proximal end of a tubular medical device rather than onto an **outer** surface of the hub.

Heck teaches a hemostasis valve wherein the diameter of said opening formed by said annular sidewall is less than a diameter of said cavity (see figure 3) so that the valve assembly is adapted to snap fit onto an **outer** surface of a hub (see figure 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tearable valve of Lee with the snap fit arrangement of Heck to be able to use the valve in conjunction with a splittable sheath having a hub with tabs (see figure 2).

Lee and Heck teach the hemostasis valve as generally claimed, but fail to teach a second membrane in the valve assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second membrane in the valve assembly, since it has

been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Response to Arguments

4. Applicant's arguments filed 7/11/08 and 9/04/08 with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763